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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/672,318

09/26/2003

Robert G. Rani

N-32720A/USN

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1095

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08/14/2007

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER

NICOLAS, FREDERICK C

ART UNIT

PAPER NUMBER

3754

MAIL DATE

DELIVERY MODE

08/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/672,318

Applicant(s)

RANI, ROBERT G.

Examiner

Frederick C. Nicolas

Art Unit

3754

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-9, 11-19 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-9, 11-18 and 23 is/are rejected.
- 7) ☒ Claim(s) 19, 21 and 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see pages 2-4, filed 6/1/2007, with respect to claims 2,11,23 have been fully considered and are persuasive. The rejection of claims 2,11,23 has been withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 2-4,8,11-14,18,23 are rejected under 35 U.S.C. 102(e) as being anticipated by Knierbein 6,485,479.

Knierbein discloses a closure device for a flexible container (26) containing a medical fluid (col. 4, ll. 49-59), which comprises a boat-shaped base section (3) having a top wall (2), a bottom wall, the base section adapted, to fit the flexible container as seen in Figure 6, a mid-section (4) connected to the top wall, a support connected to the mid-section see Figure 1 for the location of the support, a cylindrical member (17) extending through the base section, the mid-section and the support as seen in Figure 1, the cylindrical member having a first opening in the base section and a second opening in the support as seen in Figure 1, the cylindrical member adapted to allow the

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medical fluid to flow therethrough and exit the flexible container (col. 3, ll. 58-67 onto col. 4, ll. 1-20), a first seal (5) blocking the cylindrical member and capable of being breached, and a second seal (18) covering second opening and capable of being defeated, wherein a portion of the cylindrical member between the first seal and the second seal defines a chamber as seen in Figure 1, the first seal comprises a weakened section (13), a spike set (19), the base sealingly attached to an edge of the container as seen in Figure 6.

Note: the applicant is advised that any action following the words "adapted for" and/or "capable of" in the claims indicates an intended use for the product and does not limit the structure of the product in the claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 5,16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knierbein 6,485,479 in view of Babson 4,559,052.

Knierbein has taught all the features of the claimed invention except that the second seal is a peelable foil. Babson teaches the use of a second seal (3) being a peelable foil (col. 2, ll. 49-58).

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the second seal of Knierbein to be made of peelable foil as taught by Babson in (col. 2, ll. 49-58), in order provide a seal that is impervious to air.

6. Claims 6-7,17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knierbein 6,485,479.

Knierbein has taught all the features of the claimed invention except that the cylindrical member has a diameter from about 0.5 mm to about 12 mm.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cylindrical member of Knierbein to have a diameter from about 0.5 mm to about 12 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. As per MPEP 2144.05

7. Claims 9,15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knierbein 6,485,479 in view of Fowles 4,836,397.

Knierbein has taught all the features of the claimed invention except that the chamber is sterile after the closure device has experienced a sterilization process. Fowles teaches the use of a closure (10,12) being sterile after the closure has experienced a sterilization process (col. 4, ll. 1-5).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize Fowles' teaching onto the closure device of Knierbein, in order to allow the container and its contents to be in a sterile sealed environment.

Allowable Subject Matter

8. Claims 19,21-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

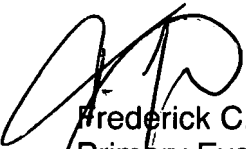
Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick C. Nicolas whose telephone number is (571)-272-4931. The examiner can normally be reached on Monday - Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver, can be reached on 571-272-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FN
August 8, 2007

 8/8/07
Frederick C. Nicolas
Primary Examiner
Art Unit 3754